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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/832,159	04/10/2001	James Brady		8503

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EXAMINER	
DUFFY, PATRICIA ANN	
ART UNIT	**PAPER NUMBER**
1645	10

DATE MAILED: 04/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/832,159	BRADY ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 July 2003, and 16 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESPONSE TO AMENDMENT

The amendment filed 7-15-03 has been entered into the record. The supplemental response and declaration filed 9-16-03 have been entered into the record. Claims 1-11 are pending and under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Withdrawn

The rejection of claims 1, 2, 3, 4, 5, 6, 7, 8 and 9 under 35 U.S.C. 102(e) as being clearly anticipated by Matson et al (U.S. Patent No. 6,287,516, filed July 10, 1998) is withdrawn in view of Applicants' arguments.

Rejections Maintained

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for reasons made of record in Paper No. 6, mailed 2-6-03.

It is noted that Applicants arguments do not independently addresses issues of record for the individual rejections and address 35 USC 112 in its entirety. Applicants arguments appear to intermix the issues of record. Therefore, the examiner has tried to respond to individual arguments relative to each of the particular rejections of record.

Applicant's arguments have been carefully considered but are not persuasive. Applicant argues that the specification discloses a number of polymeric materials that can be used to make the instantly claimed particles and reference claims 9-11. This is not persuasive, the generic claims are not limited to crosslinked polymeric materials. The number of actual particles in the hemofiltration device is not an issue. The written

description is limited to specific co-polymeric materials, the claims are drawn to any particle or bead. Applicant argues a more limited embodiment than is found in the broadest claims. Reiteration of the dependent claim does not provide for the claimed genus that is not linked by structure and function. The claims are not limited to co-polymers or polymers in general and the specification does not support by way of written description the generic particles described only by function and not the combination of specific structure and function. Applicants arguments are therefore not commensurate with the generically claimed invention. Declarant's assertions are not dispositive of this issue because they lack extrinsic support.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants arguments have been carefully considered but are not persuasive.

The specification fails to teach how to make and use the claimed invention. The written description of the specification is limited to two specifically created copolymers that are treated to have specific physicochemical absorptive characteristics based on the specific chemical composition. The specification fails to teach that these particles are effective to treat infections or sepsis in the manner contemplated by the specification which is withdrawing of blood from the patient, passing it through the system, which includes the hemocompatible blood particulate polymeric material and then returned back to the patient. While Applicants amendment to the specification clarifies the issue with respect to the specific exemplification of specific particles however, the specification still teaches that the function of the polyvinylpyrrolidone is to produce a hydrophilic shell in a separate reaction (see page 12, lines 10-13) and it is still unclear how this claimed particle is produced with the claimed pore sizes. The pore size of the final particle is not

measured nor reported in the specification as filed and the pore size as claimed is related to the particle per se and not to the hydrophobic core. Applicants have described a core and shell configuration and not reported the pore size of the final product (i.e. hydrophobic and positively charged) and as such it is still not clear how to make such given the limited teachings of the specification. The claims do not recite a "porous hydrophobic core" having a few positively charged groups. As such, Applicants to the specification do not clarify this issue. Applicants assert that it is well known in the art how to produce polymeric particles with different pore sizes, and the technique is well known in the art. This is not persuasive, it is an assertion unsubstantiated by either extrinsic or intrinsic evidence and moreover provides limitation of "polymeric particles" which is not a limitation of the claims. Applicants assert that removal of cytokines and superantigens and endotoxin will treat serious infections and sepsis pursuant to page 7. Applicants arguments are not persuasive because the lack extrinsic or intrinsic evidence of effective cytokine, superantigen and endotoxin binding. The unsubstantiated assertion in the specification lacks evidentiary support. There are no teachings of any of the claimed particles effectively removing the claim targets. While endotoxins, cytokines and superantigens can mediate squelae of serious infections and sepsis, this specification lacks evidentiary support that the particles are effective in adsorbing such molecules and therefore lack the correlation with adsorbents in the art.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained for reasons made of record in Paper No.6, mailed 2-6-03.

Applicants' arguments have been carefully considered but are not persuasive. Applicants assert that in the adsorption technique, both in science of adsorption and in industry which uses adsorption the above mentioned terms are generally known and well

established. Applicants' assertion is unsupported by either extrinsic or intrinsic evidence of record. Applicants' argue that the by the art definition a hydrophobic material is a material which repels aqueous media, while a hydrophilic material is a material which attracts aqueous material. This is not persuasive, these limited definitions are not supported by the specification as filed and Applicants' have not provided extrinsic evidence to support such. The common definitions of hydrophilic as a property indicate that it is a molecule as having an affinity for water; capable of uniting with or dissolving in water (not aqueous media). Hydrophobic and hydrophilic are not absolutes inasmuch as many compounds have "partial solubility" in water or benzene. For example, how can the claimed hydrophilic particles dissolve in water ? What is "affinity" and what degree of affinity is required to be hydrophilic ? Applicants also argue that since the materials of the present invention are polymers, it is well established in the polymeric technology that polar polymers are hydrophilic and non-polar polymers are hydrophobic. This again is not persuasive, the claims are not drawn to polymeric particles which are polar or non-polar. Applicants argue that that in the adsorption technique in both in science and industry which uses adsorption, the above methods are generally known and well established. Applicant points to the specification on page 10, paragraph 2 and page 11, paragraph 2 in which the size of the pores of the particles are specifically presented. This is not persuasive as previously set forth these terms have substantial overlap in the definitions in the specification and as such there is substantial overlap of macroprous and mesoporus. Therefore one skilled in the art would not be able to determine the metes and bounds of the claim for infringement purposes since there is substantial overlap in the defined sizes of the pores (see pages 10-11). Given, the specifically recited overlap in the size range, one skilled in the art would not know that they are infringing in the overlapping range, given the exemplification of the specification. Applicants have not responded to the issue: Are particles pore sizes from 20-50 nm macroporus or mesoporus ? With respect to general knowledge in the art of these terms, this is an unsubstantiated assertion and is not

supported by the prior art. Because of the lack of precision of these terms and the assigned overlap one of skill in the art would not be able to ascertain if the particles in these overlapping ranges of the specification are macro or mesoporus.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matson et al, (U.S. Patent No. 6,287,516, filed July 10, 1998) in view of Davankov et al (U.S. Patent No. 5,773,384).

Applicants argue that the general statement about the possibility of using certain particles or even different particles does not provide disclosure for any hemocompatible material that would be similar or identical to the material defined in claim 1. This is not persuasive, Matson et al specifically suggest the use of combinations of particles that are uncharged and charged for treatment of sepsis to remove the identical constituents. The combination of Matson et al and Davankov et al provides for a combination of particles made from components identical to that claimed herein and as such, the combination meets the limitation of the claims. Matson et al provides specific motivation for combining multiple particles of different configurations (column 6, lines 32-67). Applicants argue the references individual and not the references as combined. Each is taught separately for use in treatment of sepsis and combination of multiple particles is specifically suggested by Matson et al and logically flows from their being individually taught in the art for the same purpose (treatment of sepsis). Moreover, the courts have held in *In re Kirkhoven* (205 USPQ 1069, CCPA 1980) that "It is prima facie obvious to combine two compositions each of which is taught by prior art to be useful for the same purpose in order to form third composition that is to be used for the very same purpose:idea of combining them flows logically from their having been individually taught in the prior art." The sole component of the device is the combination of two adsorptive particles and nothing more. There is specific suggestion in Matson et al to combine multiple particles. The particles of the prior art are made from the same components as the claimed

particles and as such the combination is prima facie obvious. Applicants argue that the art must suggest applicants result, providing for efficiently removing simultaneously to reliable prevent septic shock. This is not persuasive, the particles as combined would perform the same function. Matson et al teach that the particles can be combined in the same chamber or in sequential chambers. The recited limitation of "simultaneous removal" does not structurally limit the article or the particles therein, nor does it define over the prior art. Further, Applicants are incorrect in asserting that the motivation must suggest Applicants result. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. In re Linter, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972) (discussed below); In re Dillon, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991) (discussed below). Although Ex parte Levengood, 28 USPQ2d 1300, 1302 (Bd. Pat. App. & Inter. 1993) states that obviousness cannot be established by combining references "without also providing evidence of the motivating force which would impel one skilled in the art to do what the patent applicant has done" (emphasis added), reading the quotation in context it is clear that while there must be motivation to make the claimed invention, there is no requirement that the prior art provide the same reason as the applicant to make the claimed invention. Applicants further argue that the invention is a system in which the blood passes through a material which operate in a new and different ways used jointly to fight infection is an efficient and highly advantageous way. This is also not persuasive, the claimed system comprising two particles is not different than the system as combined. Applicants reference to *Ex parte King*, is not on point, the art provides a direct suggestion of the combination of multiple particles made by the same materials as claimed. Applicants argue that that the decision logic is on point here because a specific structure can not be considered obvious over a general teaching knowledge of some materials. This is not persuasive, the is no specific chemical structure

claimed. The claims are extremely broadly drafted and recite particles made from the same monomers as in the art. As such, in contrast to the case law cited, Applicants are not claiming a particular chemical structure that is not taught by the art. Applicants again argue that there is no motivation to combine the particles. This is not persuasive, Matson et al provides specific motivation. The art as combined provides for the same chemical structures of the particles claimed herein. Applicants specifically exemplified system in the specification is NOT claimed herein. In contrast to all of the case law relied upon by Applicants, *no specific chemical structure is claimed herein. As such, all of the relied upon precedent is not on point.* Applicants claims are as broad as the prior art. The art teaches particles made by the same monomers as recited in claim 9. There is no chemical structure recited in the claims that distinguishes the particles of the prior art as combined from the instantly claimed particles. Applicants, misapprehend the relied upon case law. The claims are not drawn to a particular chemical species that is nonobvious over a genus that encompasses the species. The claims are clearly and unambiguously drawn to a genus, as is the relied upon art. As such, the claims do not distinguish over the art. For the foregoing reasons the rejection is maintained.

The declaration of unobviousness has been treated as a declaration filed pursuant to 37 CFR 1.132. The declaration filed 9-16-03 is insufficient to overcome the rejection of claims 1-11 based upon Matson et al, (U.S. Patent No. 6,287,516, filed July 10, 1998) in view of Davankov et al (U.S. Patent No. 5,773,384) as set forth in the last Office action because it expresses in an opinion format the legal position asserted by Applicants in the responses 7-21-03 and 9-16-03. The declaration provides no extrinsic evidence. As such the conclusory statements of the inventor are no more probative of nonobviousness than the same statements in an applicant's specification, in the absence of factual supporting evidence or indicia of nonobviousness. Ex parte Gray 10 USPQ2d 1922 (BPAI 1989).

Similarly, counsel's unsupported arguments and allegations of unobviousness, cannot take the place of clear and convincing evidence of unobviousness. Ex parte C 27 USPQ2d 1492 (BPAI 1992). The affidavit fails in its purpose because each merely contains unsupported conclusory statements as to the ultimate legal question. In Re Buchner, 929 F2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). In re Brandstadter, 484 F.2d 1395, 1405-6, 179 USPQ 286, 293-4 (CCPA 1973).

Status of Claims

All the claims stand rejected.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-F 6:30 pm - 3:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Smith Lynette can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patricia A. Duffy

Primary Examiner

Art Unit 1645